Applying a risk matrix to biologics manufacturing remediation: a teaching exercise

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ABSTRACT

In today's world of competing resources, it becomes necessary to find a way to prioritize many business endeavors. In this in-class exercise, students are asked to assist the Director of Plasma Quality and Regulatory Operations (D PQ/RO) and her staff members in prioritizing the remediation activities needed to prepare a slate of recently purchased plasma centers for Food and Drug Administration (FDA) licensure. The parent company, biologics giant Meridian International, recently purchased 30 plasma centers to grow that aspect of its supply chain, as plasma is a key component in several of its product lines. Although 15 of these centers are already licensed by the FDA, 15 are not; those that are not are unknown in terms of their FDA compliance and will need remediation to be successful in their FDA licensure quest. A risk matrix is used to determine the scheduling sequence of each of these 15 centers in terms of remediation support for FDA licensure. Students are challenged to discuss the validity of the use of such a matrix, to propose a remediation schedule for the centers, to provide other uses for the matrix other than remediation prioritization scheduling, and to explain how such a matrix might be constructed for other industries.

The exercise presents two approaches to classroom execution, and it provides discussion questions to assist in its implementation. This exercise is unique in that it allows the student to consider prioritization of activities in regulated industries, which may use different determinants of risk other than financial.

Keywords: Risk Matrix, Risk Prioritization, Resource Allocation, Operations Management, Process Performance, Operations Risk

INTRODUCTION

This paper presents an in-class exercise that may be used to facilitate students' understanding and management of operational risk, specifically regulatory risk. The exercise focuses on biomedical organizations, which use an interdisciplinary approach to technological and scientific advances in an effort to improve public health care, often through the manufacturing of biologics (Stirling, 2006). Due to the vital and delicate nature of their work, these organizations must comply with a wide range of government regulations, which in the United States are overseen by the Food and Drug Administration (FDA). If an FDA inspection finds a biomedical organization to be noncompliant, the agency is authorized to demand corrective action. Further complicating their work, biomedical organizations must also juggle the demands of several stakeholders, including the Voice of the Business (VoB), the Voice of the Customer (VoC), and the Voice of the People (VoPp). Although presented as a hypothetical scenario, this exercise is an application based from an actual business case, previously published (Walters and Barneva, 2017).

Biologics are distinguished from standard drugs by their production from natural sources, including living tissues; therefore, biologics are much more vulnerable to microbial contamination than artificially manufactured products, and require a stricter regulatory regime for their manufacture, storage, and transportation. The biologics that biomedical organizations produce may include drugs, vaccines, blood and blood components, tissues, gene therapies, and allergenics, among others (US FDA, 2015). Licensure by the FDA is necessary for a biomedical organization to engage in product commerce. A firm may produce material to incorporate into a final biologic, and even manufacture a biologic without an FDA license; however, the product cannot enter the marketplace until licensure is achieved. That includes markets outside of the United States, where further processing of a biologic raw product, such as plasma might occur.

It is not unusual for a US firm to have minor violations of the Code of Federal Regulations, resulting in citations, but if the FDA perceives the violations as a real health risk, the consequences for the organization can quickly become serious. The FDA may choose to issue a warning letter that explains the violation and provide a timeframe in which this must be corrected (US FDA, 2016), or the agency may seek a consent decree that mandates particular changes and is enforced by the Department of Justice (Slota et al., 2013). The organization could face increasing scrutiny, and its license to sell its biologics may be severely restricted or even revoked (Slota et al., 2013).

Thus, it is critical that biomedical organizations manage their businesses to ensure sustainable FDA compliance, as non-compliance can represent a death knell for an organization's business future.

THE CONTEXT

Meridian International has been a successful player in the biomedical field for years. Its specialty products consist of vaccines and medications manufactured from human plasma proteins. The proteins in the plasma are separated by a process known as fractionation, and Meridian International has agreements with several fractionators in Europe that purchase the plasma from Meridian and other biologic manufacturers, conduct the fractionation, and provide the resulting intermediate product back to the final manufacturers of vaccines and medications. This agreement works well for Meridian in that the fractionation process as outsourced is cheaper than if Meridian took on that process itself; further, fractionators are subject to various external inspections and assessments, and this arrangement allows Meridian to be free of that burden.

To ensure an ongoing supply of this human-based material, Meridian has opened and operated 30 plasma centers across the United States over the years, with each drawing approximately 200 units per day of plasma, a source of plasma proteins. With the advent of new treatments and the expansion into global markets, Meridian's forecasting for various products has identified the need for growth in its human plasma supply chain. The company realized that this material would be needed sooner rather than later and opted to acquire an existing plasma organization rather than build and implement its own plasma facilities.

Meridian sought to acquire a company with approximately 28 plasma collection sites dispersed throughout the country; additionally, it sought for these centers' output to approach that of its own current centers, at approximately 200 plasma units per day. Meridian understood that FDA licensure of acquired sites would assist in generating revenue more quickly; thus, it wanted at least half of the sites to already possess an FDA license, and the remaining to be ready for licensure in the 18 months following their acquisition.

Meridian found the ideal target for its acquisition in Biocash, a fledgling plasma firm that sought to become a major supplier to an array of European biologics manufacturers but struggled with its inability to overcome capital investment difficulties and the mismanagement of international concerns. Consequently, many of their anticipated European customers found other plasma services; in fact, many began their own backward-integration strategies. Further, Biocash's investors wanted cash, which Meridian had in ample supply.

The Players

The names of these exercise players are purely fictitious and convey a humorous sense of their personalities. This approach helps to engage students as they interact with the exercise.

Ida Doitright is the Director of Plasma Quality and Regulatory Operations for Meridian International's Plasma Operations Division. A stickler for detail, she has substantial experience with the organization. She reports directly to the Vice President of Quality and Regulatory Operations at Meridian, Dr. Toby Ornottobe. While Dr. Ornottobe has limited quality and regulatory operations experience, he is incredibly intelligent and well-respected in the field of biologics. Due to his inexperience, he relies heavily on his quality and regulatory operations directors, such as Ida. He reports directly to the CEO of Meridian International, Dr. Wanda Moore-Cashdollar.

Ida's staff consists of four individuals with excellent regulatory acumen, quality data analysis skills, and quality and regulatory auditing skills. First, Nahla Nonkhanformánce is a certified quality auditor (CQA) through the American Society for Quality. She has been Ida's assistant and friend for years, as they began their quality careers together with another biomedical manufacturer and followed very similar career paths. Nahla has a great deal of empathy for those she audits as well as the ability to decipher the objective evidence identified during operational audits and establish if the evidence represents true operational deficiencies or simply "noise" or "isolated incidents" in the process. She is well-regarded in the company, and operational departments do not seem to mind her auditing them!

Jill Willkillya is another CQA who has been with Meridian for quite some time. She is incredibly detail-oriented and is well-versed in regulations, which she can recite chapter and verse—for instance, she provides remarkable protection for Meridian in terms of regulatory compliance. She is also well-regarded in the company, but the operations divisions do seem to resist her auditing. Ida often assigns Jill and Nahla to the same audits to work as a team, as their personalities tend to offset each other.

The third member of the team is Liliya Analitics, a master-level engineer with an MBA who enjoys "unpacking the data." Liliya's job involves evaluating the data streams

within Meridian to identify strengths and weaknesses in its plasma operations. She also assists Nahla and Jill in preparing for audits by observing the data streams within the operational area to be audited and recommending sampling strategies for records and observations to maximize the detection of nonconformance.

The last member of Ida's team is Jenn Graphit, a Six Sigma black belt with degrees in management and graphic design; her specialty is process improvement and the visualization of data to facilitate such improvement. Jenn's role includes using graphic tools to illustrate the strengths and weaknesses in Liliya's data and Jill and Nahla's reports. She further assists in establishing improvement teams to act on this information.

The Challenge

Meridian International recently purchased 30 plasma centers from Biocash to increase its supply chain's human plasma component, which is the key in several of its product lines. Although 15 of these centers are already licensed by the FDA, 15 are not. The latter unlicensed locations have been collecting plasma, but that product cannot be introduced to the market until FDA licensure is secured. This has resulted in substantial amounts of product left unconverted to cash through final product incorporation. An agreement was reached in meetings with the FDA to have it assess these unlicensed centers for licensure within a 12-month timeframe, with the first site to be evaluated in six months from the final acquisition date. Thus, all the centers will be licensed within 18 months, assuming they are all compliant and eligible for licensure. Meridian recognizes that the unlicensed sites will need to be evaluated and prepared for licensure, a process Meridian terms "remediation." Thus, the following questions arise: How should these sites be prioritized for remediation? What should the schedule be? What should be the remediators' focus once on site?

The Model

Liliya had an idea for the remediation, as she had just attended a conference session exploring the use of a risk matrix approach to decision-making (Walters and Barneva, 2017). This matrix can plot the probability of a negative event against the severity of the event's consequences. Leaders considering these two factors—frequency and severity—both objectively and systematically can better position themselves to prioritize the risks that their organizations face (Allen, 2013). Risk matrices are used in a variety of applications. For example, Prasad (2011) describes the use of such matrices to assist organizations in identifying enterprise risk regarding effectiveness of operations, organizational compliance, and reliability of financial reporting. Risk matrices are often used in the safety industry. Baybutt (2013) describes using a risk matrix to determine the performance level of safety equipment, while further offering mechanisms to calibrate such matrices for process safety concerns (2015).

However, the risk matrix requires consensus in its construction to produce worthwhile, actionable results. Additionally, risk matrices are not perfect models, but they do indeed offer a straight forward methodology for decision-making, given their limitations (Duijm, 2015). Frequency and severity are the most common metrics for a risk matrix, yet stakeholders may disagree on how to assess these variables (Lozier, 2011). Thus, building a risk matrix is not a simple statistical process but may involve extensive consultation with stakeholders and experts, with each individual leaving his or her mark. After considering the paper presented at the conference that Liliya attended, a 5 x 5 frequency/severity matrix was chosen (Walters and Barneva, 2017).

Frequency

The frequency aspect of the matrix proposed by the paper relied on a system of deviation or nonconformance codes denoting the irregular or unsuccessful events encountered as a part of collecting, processing, and distributing the product (Walters and Barneva, 2017). These codes might read as, for example, "Pr-A-23: Product out of temperature," "Pr-C-07: Lack of cooling," and "Er-M-42: Missing unit." A biomedical organization could use these codes to more easily track, document, and manage its problems; it could more easily aggregate its data when considering the causes of any issues, and actions that might correct them. Although they are lagging indicators of performance, these codes are vital to biomedical organizations, and all manufacturers track this data. Thus, Biocash would have such data available, and Meridian could access this data.

The first step proposed in the paper involves defining frequency (Walters and Barneva, 2017). For example, five levels of frequency exist in the 5 x 5 matrix: frequent, likely, occasional, seldom, and improbable. All deviation codes reported in one calendar year were totaled to define these levels, and a histogram of their frequencies was created. In assigning each code to a calendar year, the researchers used the code's date of discovery, rather than its date of occurrence; this choice recognizes that some issues might occur undetected, and therefore, not properly reflect process performance. The histogram was then scrutinized to identify five "buckets" of data ranges that could be used for the operational definition. However, performance predictability was also determined as important, as the frequency of nonconformance might not be the only predictor of a system's historical performance.

The deviation codes were grouped and mapped into a more manageable system of controls to further refine the matrix's frequency aspect in terms of performance predictability (Walters and Barneva, 2017). These controls represent points in an operational process that must adequately function for the operational system to meet its goal. The FDA's evaluation of a firm depends on the operational systems through which the end product is manufactured, each of which is briefly explained below:

- Quality Assurance System (QAS),
- Donor Eligibility System (DES),
- Product Processing System (PPS),
- Quarantine/Inventory Management System (QIMS), and
- Product Testing System (PTS) (US FDA, 2016).

The QAS ensures compliance with current good manufacturing practices (US FDA, 2016). As a part of the QAS, all critical inputs to the biologic product are reviewed and approved by a quality unit. The QAS must validate the processes to verify that they match the expected outcome. This system also reviews the hardware and software used in manufacturing, the quality of the supplies, the training of human operators, the procedures employed, and the manufacturing site's conditions. Finally, the QAS handles product returns and defective products.

The DES ensures compliance with regulations concerning the donors of biological material. This system includes verifying that donors are properly identified and evaluated for eligibility in terms of their short- and long-term health, and their interval between donations, and properly informed of any health risks involved in their donation. These procedures ensure that the biologic will not be contaminated by any disease from the donor (US FDA, 2016).

The PPS ensures compliance with regulations for processing the biologic, from the collection of its source material to how the product is labeled (US FDA, 2016). This system oversees the gathering of raw material, such as a blood draw or bone marrow donation and the biologic's preparation and final labeling, with particular attention to sterility in each step.

The QIMS ensures compliance with regulations that protect the public against unsuitable products (US FDA, 2016). This system verifies that the donor was generally eligible to donate and in good health when the raw material was collected, and that the resulting biologic has been adequately tested.

The PTS ensures compliance with regulations to check the raw biological material for any disease that the biologic might pass to the recipient or any condition that might be transmitted. These diseases could range from requiring minor medical intervention to life-threatening infections (US FDA, 2016). This system oversees the collection and testing of samples from the biological material, and the actions taken in response to the test results.

Once these nonconformance codes were mapped to the critical processes within each operational system, the next step was to examine individual codes' total frequencies. The codes for the system of controls that supported quality functions were grouped into monthly totals for a period of 45 months. This data allowed the team to observe the control's baseline behavior and detect any variations (Walters and Barneva, 2017).

This monitoring continued in a rolling 45-month window, with each new month of data removing the oldest month from the charts. This process ensured that the charts would not become cumbersome and permitted the team to use a statistical process control (SPC) in the form of u-charts, or SPC charts that plot the defects per unit over time. U-charts are an important tool because they can adapt to different sample sizes, and they consider that not every unit with defects must be discarded (Minitab, 2016). By identifying out-of-control conditions as defined by the SPC rules, the u-charts informed the team about any abnormalities in the process, such as increases in frequency rates, upward trends, or general instability.

Certain Western Electric rules were used to craft the SPC rules for out-of-control conditions. The data under standard conditions fit a normal (Gaussian) distribution—68% of the data points lie within one standard deviation of the mean, 95% within two standard deviations, and 99.7% within three standard deviations. The distribution is symmetrical about the mean, and the mean is equal to the median and the mode. Under out-of-control conditions, the data fails to meet one or more of these criteria.

The paper used the following definitions from the Western Electric rules (Quinn-Curtis Inc., 2016):

- Freak data point: The most recent data point is more than three standard deviations from the mean. This data point is very unlikely to have resulted from the normal process (0.3% chance or lower).
- Freak pattern: Of the three most recent data points, two are more than two standard deviations from the mean in the same direction. This pattern is very unlikely to have resulted from the normal process (1% chance or lower).
- Second freak pattern: Of the five most recent data points, four are more than one standard deviation from the mean in the same direction. This pattern is unlikely to have resulted from the normal process (approximately 3% or lower).
- Shift: Eight consecutive points lie on the same side of the mean. This pattern is very unlikely to have resulted from the normal process (approximately 1%).
- Trend: Seven consecutive points indicate a continuous increase or decrease. This pattern is very unlikely to have resulted from the normal process (approximately 1%).

The paper that Liliya reviewed defined an out-of-control pattern as a shift, trend, or freak pattern, and an out-of-control point was defined as a freak data point. Such conditions escalated the risk in terms of frequency (Walters and Barneva, 2017).

Severity

An interdisciplinary team created the column headers for the risk matrix. This team included a variety of professionals in the field, such as physicians and experts in operations, regulations, and quality assurance. These individuals evaluated the groupings of nonconformance codes for each critical process within the operational systems and assigned the groupings into one of five risk categories to reflect the most significant risk indicator for each individual nonconformance code within the critical process. The column headers were determined as negligible, minor, moderate, critical, and catastrophic. Each of these categories was operationally defined with risk indicator descriptions, as noted in Figure 1 (Appendix) (Walters and Barneva, 2017).

Risk Matrix

The team then combined the risk indicator definitions with the frequency column to reach a consensus on a numerical "risk level" for each cell, with 1 being the highest and 25 being the lowest. In addition to this quantitative representation, the team overlaid a streetlight-based color coding to indicate each risk factor's urgency. A dark green color represented "monitoring," while light green represented "corrections required." Yellow signified an "immediate action needed, but would not suspend operations," while red required "immediate attention, with a risk of suspending operations." Figure 2 (Appendix) illustrates the final risk matrix (Walters and Barneva, 2017).

The risk indicator for each operational system (e.g., DES) would reflect the most serious risk indicator within the process' nonconformance grouping. For example, if a critical process in the DES was determined as a risk level of 3, while its other critical processes were of lesser numbers, then the risk level of 3 would prevail.

The Pitch

Promptly at 2:00 p.m., Ida assembled her team on another conference call. Liliya had organized an impressive 15-minute slideshow for the group to explain the risk prioritization model she had learned about at the conference. Ida then asked for comments and questions.

Nahla felt this might be an appropriate model, and especially as Jenn indicated that she could automate the data pull to generate the necessary statistical process control charts. Jill also believed it could be implemented but was concerned with grouping the nonconformance codes. Some nonconformance codes were specific, such as "collection of product start time not documented," while others were more general, such as "no documented supervisory review," which could occur in any process. Jenn posited that the incredibly specific codes were really "driving" codes, which provided the best indication of how a process point behaved, and that these driving codes should be the only ones considered. Jill was hesitant, in that the FDA's regulators would want to know exactly how the codes were determined as driving codes versus general codes. Ida and her team believed this was a valid point that they had to weigh carefully if this model was employed.

Jenn reminded the team that if this model was used, they would have to determine the frequency buckets similar to the paper's model by way of histogram analysis. She assured them this should not be difficult, but they could not lose sight of the need to do it. She also expressed confusion as to what period of time would be evaluated to determine whether out-of-control conditions existed. For example, if a freak data point occurred six months ago in the control chart, did that represent a "current" out-of-control condition? The team determined that a three-month period was more sensible, as senior management conducted a

management review every three months, and this time frame would coincide with that schedule.

Ida and her crew decided by three o'clock that this model would be their confirmed narrative. Jill and Nahla were tasked with mapping the nonconformance codes to the critical processes within each system, while Liliya and Jenn were tasked with establishing the frequency buckets, building the process control charts, and finalizing the risk matrix.

Set 1: Discussion Questions for Students

1. Do you think this model might be suitable for Meridian to use? Why or why not?
2. If this model were used, do you think all codes should be employed or just "driving" codes? Why? If just "driving" codes were used, describe one way to determine what those codes are.
3. What should be the "period under review"? How would you defend that time frame to the FDA if asked?

RESULTS

After an analysis of the code usage, Nahla and Jill determined that only the "driving" codes would be used and mapped the "driving" codes to each system's critical control processes. They found that generic codes were infrequently designated, and therefore, did not contribute any significant frequency to the frequency buckets.

Additionally, Biocash's nonconformance management system used a risk code for each individual nonconformance code, which Nahla and Jill could translate to the model's risk indicator definitions. Due to time constraints, Nahla and Jill contacted only a few experts in Meridian to lend credibility to their mapping and risk indicator translation—the Chief Medical Officer, Dr. Max Alswell, and the Senior Director of Operations Management, Jed I. Knight.

Liliya and Jenn constructed a histogram of all nonconformance codes for each of the 15 sites under review, with substantially similar results. Thus, the bucket categories were harmonized so one matrix could be used; Figure 3 (Appendix) illustrates their results.

They also generated all the statistical process control charts based on the buckets provided by Jill and Nahla.

The team created their schedule using the same matrix provided in the conference, but now had their own unique data to combine with it and five systems to judge. Each staff member was assigned a system and evaluated that system and its critical control points for each of the 15 sites. Figure 4 (Appendix) illustrates these assignments.

The evaluation was complete for the operational system by Friday morning, with each staff member posting the results. Figure 5 (Appendix) notes the risk level results for each site.

The team reviewed the results but did not reach a full consensus on the priority. Some felt that the priority should be set by observing the lowest mean score for each site, as the lower the risk number, the more critical the issue. Other team members felt the priority should be set by simply identifying the lowest risk number for each site, and set the priority based on that number. One member indicated that priority should be set in terms of the risk level mode, with first priority being assigned to those locations with the lowest modes.

Set 2: Discussion Questions for Students

1. What approach should Meridian take in the prioritization? Why do you think this approach is superior?
2. Based on your recommended approach, what priority schedule should be undertaken?
3. Identify each remediation team's largest focus at each site.
4. If your approach leads to a "tie" between two or more sites, what might be a way to determine which site has priority?
5. Consider the risk matrix approach used by Meridian. Can you think of any other applications? Provide specific examples.

CONCLUSION

In this exercise, a large biomedical manufacturer acquired 30 plasma collection sites, half of which were not yet licensed by the FDA. The manufacturer committed to evaluate and correct any issues through a remediation process for these unlicensed sites within a 12-month timeframe, with the first site to be assessed by the FDA at six months from the date of acquisition. The manufacturer was compelled to use its finite resources to determine a remediation schedule to meet these time constraints. Additionally, the manufacturer had to determine the operational areas of focus within each site to avoid wasting time on already compliant operational processes.

By prioritizing the sites and operational areas, the manufacturer demonstrates its attention to not only the VoB through its efficient use of resources, but also the VoPp as provided by the FDA in terms of compliance. Finally, the VoC is addressed, in that FDA compliance protects and represents not only US society, but also those that may benefit from the manufacturer's products.

The anticipated outcome of this exercise is a schedule of sites to be remediated as well as a key operational focus for each site. This exercise reveals the importance of risk prioritization and how tools can be applied to assist in the management of such prioritization and across various industries. Further, it becomes apparent that human subjectivity plays an important role in risk prioritization, while various tools—such as matrices—assist in providing a layer of objectivity.

TEACHING NOTE

This exercise aims to familiarize students with a methodology to prioritize risk among various organizational operations. Understanding risk priority can assist students in their careers as they seek to allocate resources among various operations; engage in organizational changes, such as mergers, acquisitions, and divestitures; and attain organizational accreditation and regulatory compliance. This exercise also offers the opportunity to access the features of problem-based learning (Rossano, Meerman, Kesting, and Baaken, 2016) by presenting a structured problem and allowing the teacher to be a facilitator by creating a student-centered environment.

The teaching note offers options based on the time available and/or the degree to which the instructor desires students to delve into the calculations and decision-making surrounding the risk model.

Facilitators must emphasize that, although the exercise used an objective tool, subjectivity was also a vital component in the decision-making process; this subjectivity is demonstrated through the differences among potential answers to discussion questions and presentations. The process of developing a recommendation is just as significant a teaching tool as the learning of the risk matrix methodology.

Small Group Discussion Approach: Three 50-Minute Class Periods

After a foundation of risk management is provided through lecture, assign the reading of the exercise up to and including The Pitch, prior to in-class work on the exercise. During class, form small groups, instructing each group to summarize what they understood (30 minutes total). Ask a group or two to provide their summations; provide clarity in terms of the subject matter as necessary (about 15 minutes). At the conclusion of the first session, provide the Set 1 Discussion Questions.

When the class reconvenes, ask students to return to their small groups, and evaluate the Set 1 Discussion Questions (approximately 30 minutes). Call on random groups to share their answers. If necessary, complete the discussion at the next session.

Set 1: Discussion Questions for Students

1. Do you think this model might be appropriate for Meridian to use? Why or why not?

In the absence of any alternative, students will most likely indicate it is a good model, especially since it closely mirrors Meridian's objectives. Students might suggest its disadvantages, such as data integrity (for example, how does Meridian know if Biocash was adept at logging its nonconformance data?). While this might not be a perfect solution, it is a solution. Instructors can push back on the model's acceptance by asking about data integrity, the likelihood of FDA acceptance, and the ability to construct the model in a short period of time.

2. If this model were used, do you think all codes should be employed or just "driving" codes? Why? If just "driving" codes are used, describe one way to determine what these codes are.

Students will likely give varying answers here. An argument can be made for both instances, but if properly mapped, using only driving codes would give the cleanest and most straightforward approach.

3. What should be the "period under review"? How would you defend that period to the FDA if asked?

Logically, the period under review contains data that are more recent. For example, if the data move back into a state of control, then what is the point in taking corrective action? Resources should be deployed to where the issues exist, and not to where issues existed in the past. Additionally, management oversight each quarter is more likely to elevate priority issues if this model is expanded for use beyond prioritizing remediation. These points are legitimate answers for the FDA.

To prepare for the third class, provide the students with the remainder of the exercise, along with the Set 2 Discussion Questions. At the next session, ask students to return to their small groups and share their Set 2 Discussion Question answers (approximately 30 minutes). Call on one or two random groups to share their answers (20 minutes).

Set 2: Discussion Questions for Students

1. What approach should Meridian take for the prioritization? Why do you think this approach is superior?

Students will attempt to choose between the two approaches identified above. There is no correct answer to this question; students should be encouraged to evaluate both approaches and provide some basis of comparison for them.

2. What priority schedule should be undertaken based on your recommended approach?
   This answer will depend on what approach is described as a part of Set 2, Question 1.
3. In terms of each site, identify each remediation team's largest focus at each site.
   The student should recognize here that the operational system with the lowest score should be the remediation team's focus.
4. If your approach leads to a "tie" between two or more sites, what might be a way to determine which site has priority within that tie?
   Students can identify any means as a tiebreaker. One point to consider involves reminding the students that unlicensed sites cannot enter their products into commerce, so the sites with the largest inventories might be one deciding factor.
5. Consider the risk matrix approach used by Meridian. Can you think of any other applications? Provide specific examples.
   Here, students should be able to discuss how a risk matrix might be used in any number of settings. For example, in education, the frequency of missed classes might be mapped to the likelihood of graduation.

Written Submission and Peer Review: Two 50-Minute Class Periods

In this module, the exercise is used to instruct on how the model was developed; the different quality systems' role; and reinforcing the relevancy of the voices of the customer, the business, and the people. As you explain the exercise up to the Results section, students can take notes. At the end of the discussion, highlight three methods of prioritizing risk, with slides and discussion. Reinforce an understanding of the operating systems.

Distribute the exercise's Results section with the following set of questions:

1. What approach do you think Meridian should take in its prioritization? Why do you think this approach is superior?
2. Based on your recommended approach, what priority schedule should be undertaken?
3. In terms of each site, identify each remediation team's largest focus at that site.
4. If your approach leads to a "tie" between two or more sites, what might be a way to determine which site has priority within that tie?
5. Consider the risk matrix approach used by Meridian. Can you think of any other applications? Provide specific examples.

You can choose whether the written assignment is conducted individually or as a group. If time is limited for this exercise, the written assignment could be given as an individual assignment, and thus, the teacher would lead the class in an abbreviated debrief on the answer options and collect papers during the second class.

If more time is available for the third class period, a class discussion can be led on the questions, and a peer review model can be utilized. If using the peer review model, students can trade their papers with another student in the class. The teacher can distribute a rubric for students to assess the written response based on learning objectives relevant to assessment needs. The rubric might contain such items as basic spelling/grammar and the ability to present an argument with logical thinking, which focuses the peer review on an assessment of basic written communications. Other items in the rubric might include demonstrating an understanding of such relevant concepts as risk, a regulated environment, or quality systems.

In a third option for the written assessment, students in small groups would review their individual answers and come to a consensus. Each group could then provide a brief pitch on its recommended prioritization method (Question 1). If time allows, groups could debate with each other on the proposed methods and rationale. Papers are then submitted for grading by the instructor.

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APPENDIX

Figure 1: Risk Indicator Descriptions

Negligible	Minor	Moderate	Critical	Catastrophic
No risk of damage or death	Risk of temporary damage (detectable or not)	Risk of death but highly detectable; risk of permanent damage, but detectable	Risk of death but detectable; risk of permanent damage and not detectable	Risk of death and not detectable

Figure 2: Final Risk Matrix

Risk Matrix		Risk Indicator				
		Negligible	Minor	Moderate	Critical	Catastrophic
Frequency / Process Performance	Frequent Or Pattern Out of Control	17	14	11	4	1
	Likely Or Point Out of Control	18	15	12	5	2
	Occasional	19	16	13	6	3
	Seldom	24	22	20	9	7
	Improbable	25	23	21	10	8

Figure 3: Bucket Categories of Nonconformance Frequency

Code Frequency Range	Category of Frequency
0 – 49	Improbable
50 – 499	Likely
150 – 499	Occasional
500 – 1499	Seldom
1500 +	Frequent

Figure 4: Staff Member System Assignments

Staff Member	Operational System
Jill	DES
Nahla	QAS
Ida	PTS
Jenn	QIMS
Liliya	PPS

Figure 5: Risk Level Results by Site

SITE 1	Risk Level	SITE 6	Risk Level	SITE 11	Risk Level
QAS	24	*QAS*	25	*QAS*	18
DES	6	*DES*	11	*DES*	14
PPS	11	*PPS*	14	*PPS*	9
PTS	22	*PTS*	16	*PTS*	19
QIMS	4	*QIMS*	13	*QIMS*	7
SITE 2	**Risk Level**	**SITE 7**	**Risk Level**	**SITE 12**	**Risk Level**
QAS	25	*QAS*	23	*QAS*	19
DES	7	*DES*	11	*DES*	14
PPS	11	*PPS*	6	*PPS*	10
PTS	22	*PTS*	16	*PTS*	18
QIMS	3	*QIMS*	12	*QIMS*	9
SITE 3	**Risk Level**	**SITE 8**	**Risk Level**	**SITE 13**	**Risk Level**
QAS	23	*QAS*	17	*QAS*	17
DES	8	*DES*	11	*DES*	6
PPS	11	*PPS*	6	*PPS*	10
PTS	15	*PTS*	15	*PTS*	17
QIMS	5	*QIMS*	11	*QIMS*	10
SITE 4	**Risk Level**	**SITE 9**	**Risk Level**	**SITE 14**	**Risk Level**
QAS	23	*QAS*	17	*QAS*	22
DES	9	*DES*	12	*DES*	6
PPS	12	*PPS*	7	*PPS*	7
PTS	15	*PTS*	21	*PTS*	16
SITE 5	**Risk Level**	*QIMS*	10	*QIMS*	10
QAS	24	**SITE 10**	**Risk Level**	**SITE 15**	**Risk Level**
DES	10	*QAS*	18	*QAS*	18
PPS	13	*DES*	13	*DES*	6
PTS	16	*PPS*	8	*PPS*	7
QIMS	14	*PTS*	20	*PTS*	16
		QIMS	6	*QIMS*	9